DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 22, 2015

Excera Orthopedics, Incorporated
% Mr. Tim M. Lohnes
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K140547
Trade/Device Name: Excera FitRite™ Total Hip Arthroplasty System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: December 19, 2014
Received: December 22, 2014

Dear Mr. Lohnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140547

Device Name
Excera FitRite™ Total Hip Arthroplasty System

Indications for Use *(Describe)*
Total Hip Arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.
The Excera FitRite™ Total Hip Arthroplasty System is indicated for total hip replacement in the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The FitRite™ DDH Femoral Stems, Standard Femoral Stems, and Acetabular Cups are intended for cementless application; the FitRite™ Cemented Femoral Stems are intended for cemented application.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K140547 Excera Orthopedics, Inc. January 22, 2015

FitRite™ Total Hip Arthroplasty System

510(k) Summary

Submitter's Information [21 CFR 807.92(a)(1)]

Tim M. Lohnes, Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484
Phone: (203)922-0105
Fax: (203)922-0130

Orchid Design has received authorization to submit this 510(k) on behalf of the sponsor;

Excera Orthopedics, Inc.,
1188 Centre St,
Newton, MA 02459.
Establishment Registration Number: 3009752723

Date Prepared [21 CFR 807.92(a)(1)]

February 21/April 9/April 25/December 19, 2014/January 22, 2015

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: Excera FitRite™ Total Hip Arthroplasty System
Common Name: Total Hip Prosthesis
Panel Code: Orthopedics/87

DDH, Standard Stems, Cups, liners, heads, screws (Un-cemented)

Classification Name and Reference: 21 CFR §888.3358-Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented.

Class/Product Code: 2/LPH

Optimum Cemented Stem (CoCr) (Cemented)

Classification Name and Reference: 21 CFR §888.3350-Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.

Class/Product Code: 2/JDI

Predicate Device(s) [21 CFR 807.92(a)(3)]

The components of the Excera Total Hip Arthroplasty System are substantially equivalent to the following previously cleared devices;

1) The DDH & Standard Stems; Zimmer Mayo® Conservative Hip Prosthesis (K061461)

2) The Cemented stems; Zimmer CPT 12/14 Femoral Stem (K030265) and Zimmer Fitmore (K071723)

3) The Acetabular Cups; DePuy Pinnacle w/ Gripton (K071784)

4) The Acetabular Liners Screws; DePuy Pinnacle Acetabular System (K001534)

5) The femoral heads; DePuy Ultima™ Unipolar Femoral Head, (K033273)

6) The cement restrictors; Kinamed REALITY, (K922247)

Description of the Device [21 CFR 807.92(a)(4)]

The Excera Orthopedics FitMore™ Total Hip Arthroplasty System is intended to be used for primary total hip replacement in skeletally mature individuals.
The System's modular design provides a large selection of component sizes.

The System includes three stem designs; a double tapered Femoral Stem (uncemented) with the proximal metaphyseal portion CpTi plasma spray coated, a double-tapered Femoral Stem (un-cemented) with the same essential proximal taper inclusive of a distal stem portion to be inserted in the diaphysis, and the Optimum Femoral Stem (Cemented), a collarless, highly polished double-taper cemented Femoral Stem with design features known to provide reliable performance.
The System's CoCrMo Femoral Heads interlock with the Femoral Stems via a standard taper attachment, providing accurate placement and secure fixation.

There are three different uncemented Acetabular Cup designs allowing for adjunct fixation; two with specifically designed screw hole patterns, and one with protruding "spurs" designed to fixate to the previously prepared acetabular surface. The Ti6Al4V Acetabular Cups are CpTi plasma spray coated on the trabecular surface. The Ti6Al4V Acetabular Screws are available in 6 lengths from 15 to 40mm in 5mm increments.
The conventional non-cross-linked UHMWE Acetabular Liners are available in various diameters corresponding to the Femoral Heads and Acetabular Cups, and in 10 degree elevated and standard, non-elevated rim configurations.

Intended Use [21 CFR 807.92(a)(5)]

The Excera Orthopedics Total Hip Arthroplasty System is intended to be used for total hip replacement in skeletally mature individuals.

The System's modular design provides a large selection of component sizes, allowing implant geometry to be optimized.

FitRite™ Total Hip Arthroplasty System

Indications for Use:

Total Hip Arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

The Excera FitRite™ Total Hip Arthroplasty System is indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The FitRite™ DDH Femoral Stems, Standard Femoral Stems, and Acetabular Cups are intended for cementless application; the FitRite™ Cemented Femoral Stems are intended for cemented application.

Technological Characteristics [21 CFR 807.92(a)(6)]

The Excera FitRite™ Total Hip Arthroplasty System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance. The technological characteristics do not raise any new questions of safety and efficacy.

Non-clinical testing [21 CFR 807.92(b)(1)]

Testing in accordance with ASTM/ISO standards was used to evaluate mechanical performance. A summary of tests performed, results, and standards used is given below in table 5.1

In addition, coating characterization testing was performed on the subject device.

Table 5.1: Testing Summary for The Excera FitRite™ Total Hip Arthroplasty System

Standard	Test Type	Results
ASTM F2068	Proximal Fatigue	Pass
ISO 7206-4:2010	Distal Fatigue	Pass
ISO 21535:2007	Range of Motion	Pass
ASTM F1875	Taper Fretting	Pass
ASTM F2009	Femoral Head Distraction	Pass
ASTM F1820	Liner Push out, Lever out & Torque out	Pass
ASTM F543	Screw Insertion Torque & Max Torque	Pass

Clinical testing [21 CFR 807.92(b)(2)]

Clinical testing was not required to demonstrate substantial equivalence in this premarket notification

Conclusions [21 CFR 807.92(b)(3)]

Based on the information provided in this premarket notification, we believe that the subject Excera FitRite™ Total Hip Arthroplasty System demonstrates substantial equivalence to the identified predicate devices.